Louisiana Office of Public Health Laboratories	
Test Name	Dengue IgM
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86790
Synonyms	DENV IgM
Brief Description of Test	**Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.** This procedure is for the qualitative detection of IgM antibodies to DEN recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection. This assay is intended for use only in patients with clinical symptoms consistent with either dengue fever or dengue hemorrhagic fever. Positive results must be confirmed by Plaque Reduction Neutralization Test (PRNT), or by using the current CDC guidelines for diagnosis of this disease.
Possible Results	• ***Negative****:* No detectable IgM antibody; individual does not appear to be infected with Dengue virus. The result does not rule out Dengue virus infection. An additional sample should be tested within 7 – 14 days if early infection is suspected. Other Dengue virus assays such as Dengue NS1 assays, PCR or culture should be performed to rule out early acute infection. • ***Equivocal****:* Samples should be retested before reporting. • ***Presumptive Positive****:* Presence of detectable IgM antibody; presumptive infection with Dengue virus. The result should be confirmed by plaque reduction neutralization test (PRNT) or by using the latest CDC guideline for diagnosis of this disease. A positive IgM result does not indicate a recent infection because IgM may persist for several months after infection.
Reference Range	Negative
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	300 µL
Collection Instructions	Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before

	shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines. Follow the package insert for the collection tube you use. Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, onset date, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Take a venous, whole blood sample. Follow serum specimen collection devices manufacturer instructions for proper collection, separation and storage methods. • *If specimens are received >7 days from symptom onset, Dengue PCR should be ordered.* • Specimens may be stored and shipped at 2-8°C for up to 2 days from collection. • Specimens older than 2 days from time of collection should be stored frozen at -20°C or lower and shipped and received in lab frozen on dry ice. If frozen, document the date and time of freezing. • If specimens are to be shipped, they should be packed in compliance with Federal Regulations covering the transportation of infectious agents.
Causes for Rejection	Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements are also reasons for rejection.
Limitations of the Procedure	• All reactive samples must be confirmed by PRNT or by using the latest CDC guideline for diagnosis of this disease. • Since this is a presumptive positive assay, the presence of false positive and false negative results must be considered. • Serological cross-reactivity across the flavivirus group is very common. Certain sera from patients infected with Japanese

	Encephalitis, West Nile, and or Saint Louis viruses may give false positive results. Therefore, any Dengue positive sera must be confirmed with other tests. • Cross-reactiviey with Malaria IgM has not been evaluated with the DENV Detect IgM Capture ELISA. • Assay performance characteristics have not been established for visual result determination. • Assay performance characteristic have not been established for matrices other than serum. • Results from immunosuppressed patients must be interpreted with caution. • Assay results should be interpreted only in the context of other laboratory findings and the total clinical status of the patient.
Interfering Substances	• High cholesterol levels (>300 mg/dL) appear to give variable results and may affect the DENRA OD values. • High triglyceride levels (>3000 mg/dL) appear to exhibit a slight effect of raising the ISRs of low positive sera. • Hemoglobin (>1600 mg/dL) appears to affect some serum samples by lowering the ISRs.
References	Package Insert: InBios DENV Detect™ IgM Capture ELISA
Additional Information	Anti-dengue virus IgM antibody is produced transiently during primary and secondary infection. In patients with primary dengue virus infection, IgM antibodies develop rapidly and are detectable by days 3 to 5 of illness in half of hospitalized patients. Anti-dengue virus IgM levels peak at about 2 weeks post infection and then decline to undetectable levels over 2 to 3 months. In patients with secondary dengue virus infections, while the kinetics of IgM production are similar to those observed in patients with primary infections, IgM levels are significantly lower. Anti-dengue IgM antibodies also peak at about 2 weeks post infections, begin to wane thereafter, and are still detectable in about 30% of patients 2 months after the onset of symptoms.
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